Principle 1: Hazard Analysis

The first step in creating a HACCP Plan is to conduct a Hazard Analysis which identifies all of the significant food safety hazards that are associated with the operations, products, and processes. You may remember that a hazard is defined as “a biological, chemical, physical agent that is reasonably likely to cause illness or injury in the absence of its control.”

The five steps in a Hazard Analysis are:

1. List the process steps
2. Identify all potential food safety hazards
3. Determine if each hazard is significant
4. Justify the decision
5. Identify the control measure, which may be defined as “any action or activity that can be used to prevent or eliminate a significant hazard or reduce it to an acceptable level.”

1. Process Steps
   This step utilizes the flow diagrams that have been created as part of the preliminary steps. These are the steps that will listed in column one (1) of the Hazard Analysis worksheet. A Hazard Analysis worksheet is designed to ensure that all of the steps in the Hazard Analysis are completed.

2. Hazard Identification
   Next, the specific food safety hazards that are reasonably likely to occur must be identified. To aid in this process, dairy processors can consult with the FDA Hazards & Control Guide for Dairy Foods HACCP. The FDA recommends using the following set of questions when identifying hazards:

A. Ingredients
   1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?
   2. Are potable water, ice and steam used in formulating or in handling the food?
   3. What are the sources (e.g., geographical region, specific supplier)
B. Intrinsic Factors - Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.
   1. What hazards may result if the food composition is not controlled?
   2. Does the food permit survival or multiplication of pathogens and/or toxin formation in the food during processing?
   3. Will the food permit survival or multiplication of pathogens and/or toxin formation during subsequent steps in the food chain?
   4. Are there other similar products in the market place? What has been the safety record for these products? What hazards have been associated with the products?

C. Procedures used for processing
   1. Does the process include a controllable processing step that destroys pathogens? If so, which pathogens? Consider both vegetative cells and spores.
   2. If the product is subject to recontamination between processing (e.g., cooking, pasteurizing) and packaging which biological, chemical or physical hazards are likely to occur?

D. Microbial content of the food
   1. What is the normal microbial content of the food?
   2. Does the microbial population change during the normal time the food is stored prior to consumption?
   3. Does the subsequent change in microbial population alter the safety of the food?
   4. Do the answers to the above questions indicate a high likelihood of certain biological hazards?

E. Facility design
   1. Does the layout of the facility provide an adequate separation of raw materials from ready-to-eat (RTE) foods if this is important to food safety? If not, what hazards should be considered as possible contaminants of the RTE products?
   2. Is positive air pressure maintained in product packaging areas? Is this essential for product safety?
   3. Is the traffic pattern for people and moving equipment a significant source of contamination?

F. Equipment design and use
   1. Will the equipment provide the time-temperature control that is necessary for safe food?
   2. Is the equipment properly sized for the volume of food that will be processed?
   3. Can the equipment be sufficiently controlled so that the variation in performance will be within the tolerances required to produce a safe food?
4. Is the equipment reliable or is it prone to frequent breakdowns?
5. Is the equipment designed so that it can be easily cleaned and sanitized?
6. Is there a chance for product contamination with hazardous substances; e.g., glass?
7. What product safety devices are used to enhance consumer safety?
8. Normal equipment wear affect the likely occurrence of a physical hazard (e.g., metal) in the product?
9. Are allergen protocols needed in using equipment for different products?

G. Packaging
1. Does the method of packaging affect the multiplication of microbial pathogens and/or the formation of toxins?
2. Is the package clearly labeled "Keep Refrigerated" if this is required for safety?
3. Does the package include instructions for the safe handling and preparation of the food by the end user?
4. Is the packaging material resistant to damage thereby preventing the entrance of microbial contamination?
5. Are tamper-evident packaging features used?
6. Is each package and case legibly and accurately coded?
7. Does each package contain the proper label?
8. Are potential allergens in the ingredients included in the list of ingredients on the label?

H. Sanitation
1. Can sanitation have an impact upon the safety of the food that is being processed?
2. Can the facility and equipment be easily cleaned and sanitized to permit the safe handling of food?
3. Is it possible to provide sanitary conditions consistently and adequately to assure safe foods?

I. Employee health, hygiene and education
1. Can employee health or personal hygiene practices impact upon the safety of the food being processed?
2. Do the employees understand the process and the factors they must control to assure the preparation of safe foods?
3. Will the employees inform management of a problem which could impact upon safety of food?

J. Conditions of storage between packaging and the end user
1. What is the likelihood that the food will be improperly stored at the wrong temperature?
2. Would an error in improper storage lead to a microbiologically unsafe food?

K. Intended use
   1. Will the food be heated by the consumer?
   2. Will there likely be leftovers?

L. Intended consumer
   1. Is the food intended for the general public?
   2. Is the food intended for consumption by a population with increased susceptibility to illness (e.g., infants, the aged, the infirmed, immunocompromised individuals)?
   3. Is the food to be used for institutional feeding or the home?


3. Hazard Evaluation
   o Determining Likelihood of Hazards
     ▪ Product Composition and Characteristics
     ▪ Process and Handling Considerations
   o Determining Likelihood of Occurrence
     ▪ Product History and Past Experience
   o Determining Severity
     ▪ Short term exposure vs. long term exposure